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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ROMEO, DAVID S	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/005,318	HEIN ET AL.	
	Examiner	Art Unit	
	David S. Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-69 and 73-78* is/are pending in the application.

4a) Of the above claim(s) *44,46-49,51,53,66,75 and 78* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42,43,45,52,54-65,67-69,73,74,76 and 77* is/are rejected.

7)☒ Claim(s) *50* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/23/2004 has been entered.

Claims 42-69, 73-78 are pending. Applicants' election of the species of targeting molecule comprising a J chain encoded by nucleotides 1-213 of SEQ ID NO: 8 covalently linked via a peptide bond to an antigen combining site is acknowledged. Claims 44, 46-49, 51, 53, 66, 75, 78 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 31.

Maintained Formal Matters, Objections, and/or Rejections:

Double Patenting

Claims 42-48, 52-69, 73-77 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 08/782,481. It is acknowledged that Applicants will either file a terminal disclaimer or show that the claims are patentably distinct.

Claims 42-69, 73-77 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6, 7 of U.S. Patent No. 6440419. It is acknowledged that Applicants will either file a terminal disclaimer or show that the claims are patentably distinct.

Claims 42-69, 73-77 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/062467. It is acknowledged that Applicants will either file a terminal disclaimer or show that the claims are patentably distinct.

Claim Rejections - 35 USC § 112

Claim 42, 43, 45, 52, 54-65, 67-69, 73, 74, 76, 77 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue that forms (a) and contains (b) have been shown to be necessary for a targeting molecule, and therefore the written description requirement of 35 U.S.C. § 112, first paragraph, has been met. Applicant's arguments have been fully considered but they are not persuasive. Claims 42, 43, 45, 52, 54-65, 67-69 are directed to or encompass a targeting molecule comprising a portion of J chain and a polypeptide that forms (a) and contains (b). There are no structural or functional limitations to the portion. It cannot be ascertained which of

the SEQ ID NOs: in the dependent claims constitutes the minimal structure required to generate an SC-binding site. Claims 73, 74, 76, 77 are directed to or encompass a targeting molecule that contains (a), forms (b), comprises at least domain 2 of a J chain, and does not contain any of CH1alpha, CH2alpha, CH3alpha, and CL. The only working examples in the present specification (Example 3) show the targeting of various biological agents linked to "TM." What constitutes "TM" in these examples cannot be ascertained. The evidence cited by the examiner shows that although the presence of the J chain in IgA or IgM polymers is needed in order to obtain SC binding, the J chain by itself does not constitute an SC-binding site. Accordingly, a description of a J chain or J chain portion or forms (a) and contains (b) is not a description of a targeting molecule that binds an epithelial basolateral factor and is not a description of a J chain portion that is characterized in having the ability to bind to an epithelial basolateral factor. The species exemplified, identified, or otherwise described with particularity are not representative of the functional genera implied by the minimal structural limitations imposed by the claims. The skilled artisan would thus not have recognized that the inventors were in possession of the invention now claimed at the time the application was filed.

Claims 42, 43, 45, 52, 54-65, 67-69, 73, 74, 76, 77 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a targeting molecule comprising a J chain and the CH2 and CH3 domains of IgA or IgM, does not reasonably provide enablement for a targeting molecule comprising a polypeptide that forms (a) and contains (b), a portion of a J chain, and the CH2 and CH3 domains of IgA or IgM, or for a targeting molecule that contains (a), forms (b), comprises at least domain 2 of a J chain, and does not contain any of CH1alpha,

CH2alpha, CH3alpha, and CL. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants argue that forms (a) and contains (b) have been shown to be necessary for a targeting molecule, and that the skilled artisan could practice the invention without undue experimentation. Applicant's arguments have been fully considered but they are not persuasive. Claims 42, 43, 45, 52, 54-65, 67-69 are directed to or encompass a targeting molecule comprising a portion of J chain and a polypeptide that forms (a) and contains (b). There are no structural or functional limitations to the portion. It cannot be ascertained which of the SEQ ID NOs: in the dependent claims constitutes the minimal structure required to generate an SC-binding site. Claims 73, 74, 76, 77 are directed to or encompass a targeting molecule that contains (a), forms (b), comprises at least domain 2 of a J chain, and does not contain any of CH1alpha, CH2alpha, CH3alpha, and CL. The only working examples in the present specification (Example 3) show the targeting of various biological agents linked to "TM." What constitutes "TM" in these examples cannot be ascertained. The evidence cited by the examiner shows that although the presence of the J chain in IgA or IgM polymers is needed in order to obtain SC binding, the J chain by itself does not constitute an SC-binding site. Furthermore, predicting structure, hence function, from primary amino acid sequence data is extremely complex. In the absence of a minimal structure required to generate an SC-binding site a skilled practitioner would have to resort to a substantial amount of undue experimentation in the form of insertional, deletional and substitutional mutation analysis before they could even begin to

rationally design a functional TM having other than a J chain and the CH2 and CH3 domains of IgA or IgM.

Specification

The application is not fully in compliance with the sequence rules, 37 C.F.R. § 1.821-1.825. Claims 48, 53, 55, 58, 60 recite SEQ ID NOs: 114-140. However, these SEQ ID NOs: are not part of the sequence listing.

Correction is required.

Applicants' request to rely on the sequence listing filed January 17, 2001 is acknowledged. However, correction is still required. See the attached notice to comply. Furthermore, a paper copy and computer readable form of the sequence listing was filed on 08/19/2003. The submission clearly directed their entry into the present application. The sequence listing filed 08/19/2003 does not contain SEQ ID NOs: 114-140.

New Formal Matters, Objections, and/or Rejections:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 42, 43, 45, 52, 54, 56, 57, 59, 63, 67-69, 73, 74, 76, 77 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wallner (N).

Wallner discloses fusion proteins containing a portion of LFA-3 containing a functional CD2-binding domain fused to at least a portion of the Fc region of an immunoglobulin (Ig) (page 6, full paragraph 3). The Fc region is preferably limited to the hinge region and the C_{H2} and C_{H3} domains (paragraph bridging pages 24-25). In addition, Wallner also discloses multimeric forms of LFA-3-Ig fusion proteins generated by using those Fc regions, or portions thereof, of Ig molecules which are usually multivalent, e.g., IgM pentamers and IgA dimers. It is of course understood that a J chain polypeptide may be necessary to form and stabilize IgM pentamers and IgA dimers. See page 29, full paragraph 2

In the absence of evidence to the contrary, LFA-3 and a portion of LFA-3 containing a functional CD2-binding domain are biological agents. Wallner discloses that the fusion proteins inhibit T-cell activation and PBL proliferation (page 6, full paragraph 3). Insofar as the fusion proteins comprise only the Fc regions of IgM or IgA, then the fusion proteins do not comprise a full-length Ig. It almost goes without saying that LFA-3 and a portion of LFA-3 containing a functional CD2-binding domain are not native to the Fc regions of IgM or IgA. Insofar as the fusion protein comprises a J chain, then the fusion protein comprises a portion of a J chain. Claims 42, 52, 54, 56, 57, 59, 73, 76 recite structural features of the J chain. Insofar as Wallner's fusion protein comprises a J chain, then Wallner's fusion protein comprises the recited structural features and comprises an Ig heavy chain or portion thereof linked to said J chain or portion thereof. Insofar as the Fc regions of IgM or IgA do not comprises an Ig light chain, then

Wallner's fusion protein does not comprise an Ig light chain or C_L. Insofar as the Fc region is preferably limited to the hinge region and the C_{H2} and C_{H3} domains, then Wallner's fusion protein does not comprise $C_H1\alpha$. Wallner discloses a pharmaceutical composition comprising the fusion protein an a pharmaceutically acceptable carrier (page 32, full paragraph 1). The phrase "for delivery ... surface," is an intended use of the claimed composition. The intended use does not distinguish the claimed composition from Wallner's fusion proteins. Wallner discloses the preparation of recombinant or synthetic fusion proteins (page 6, full paragraph 2 and last full paragraph), wherein only those DNA sequences which encode the desired polypeptides are expressed in transformed hosts (page 17, full paragraph 1).

This rejection is being made in the alternative under 35 U.S.C. 103(a) as obvious over Wallner (N) in the event that Wallner is construed as disclosing multimeric forms of LFA-3-Ig fusion proteins generated by using those Fc regions, or portions thereof, of Ig molecules which are usually multivalent, e.g., IgM pentamers and IgA dimers, which do not comprises a J chain. It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to make multimeric forms of LFA-3-Ig fusion proteins generated by using those Fc regions, or portions thereof, of Ig molecules which are usually multivalent, e.g., IgM pentamers and IgA dimers, as taught by Wallner, and to modify that teaching by incorporating a J chain, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification because a J chain polypeptide may be necessary to form and stabilize IgM pentamers and IgA dimers. The invention is prima facie obvious over the prior art.

Claims 73, 74, 76, 77 are rejected under 35 U.S.C. 102(e) as being anticipated by Capra (U. S. Patent No. 6063905, cited by Applicants).

Capra discloses an IgA antibody consisting essentially of a VH domain fused to a first IgA1 C.alpha.3 domain including a tailpiece, a VL domain fused to a second IgA1 C.alpha.3 domain including a tailpiece, and a J-chain, wherein the VL and VH domains constitute an antigen or hapten recognition site. These antibodies are also referred to as "mini IgA" antibodies. By consisting essentially of is meant that the antibodies include only the antibody domains shown herein to be essential for dimerization and for binding of the dimers to the pIgA receptor. The invention may be further defined as the dimers of the described minimal IgA antibodies formed by disulfide bonds between the monomers and the J-chains and across the tailpieces as shown in FIG. 3B. See column 5, full paragraph 2. Of particular use is S1-1, a human monoclonal IgG1/.gamma. antibody produced by a hybridoma derived from the spleen of an HIV sero-positive patient (column 14, full paragraph 3). Thus, Capra discloses a molecule comprising a J chain covalently linked via a peptide bond to an antigen combining site that does not contain any of CH1alpha, CH2alpha, and CL. The limitations forms (a) and contains (b) and the limitations of claim 76 are structural limitations of the J chain, which Capra's molecule comprises.

Claim Rejections - 35 USC § 103

Claims 42, 54-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallner (N) as applied to claims 42, 54, 56, 57, 59 above, and further in view of Chamow (U) and Max (AP, cited by Applicants).

Wallner teaches multimeric forms of LFA-3-Ig fusion proteins generated by using those Fc regions, or portions thereof, of Ig molecules which are usually multivalent, e.g., IgM pentamers and IgA dimers, which comprise a J chain, and methods of making these fusion proteins through recombinant means, as discussed above. Wallner does not teach a human J chain.

Chamow teaches that human antibodies are much less immunogenic that mAbs derived from nonhuman species and that immunoadhesins circumvent the difficulty in obtaining human antibodies (page 52, left column, full paragraph 1).

Max teaches an isolated nucleic acid molecule encoding a human J chain (page 836, Figure 1), that comprises the amino acid sequence of SEQ ID NOs: 125, 130, 131, 133, 135, and AsnLys.

Chamow and Max do not teach multimeric forms of LFA-3-Ig fusion proteins generated by using those Fc regions, or portions thereof, of Ig molecules which are usually multivalent, e.g., IgM pentamers and IgA dimers, which comprise a human J chain, and methods of making these fusion proteins through recombinant means. However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to make multimeric forms of LFA-3-Ig fusion proteins generated by using those Fc regions, or portions thereof, of Ig molecules which are usually multivalent, e.g., IgM pentamers and IgA dimers, which comprise a J chain, as taught by Wallner, and to modify that teaching by using a human J chain, as taught by Max, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification because there would be reasonable expectation that multimeric forms of LFA-3-Ig fusion proteins generated by using those Fc regions, or portions thereof, of Ig molecules

which are usually multivalent, e.g., IgM pentamers and IgA dimers, which comprise a human J chain, would be less immunogenic. The invention is prima facie obvious over the prior art.

Claims 42, 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallner (N) as applied to claim 42 above, and further in view of Chamow (U) and Max (AP, cited by Applicants) as applied to claims 42, 54-60 above, and further in view of Cheng (A).

Wallner in view of Chamow and Max teach multimeric forms of LFA-3-Ig fusion proteins generated by using those Fc regions, or portions thereof, of Ig molecules which are usually multivalent, e.g., IgM pentamers and IgA dimers, which comprise a human J chain, as discussed above. Wallner in view of Chamow and Max do not teach multimeric forms of an enzyme generated by using those Fc regions, or portions thereof, of Ig molecules which are usually multivalent, e.g., IgM pentamers and IgA dimers, which comprise a human J chain.

Cheng teaches a receptor protein tyrosine phosphatase polypeptides (PTP)λ, wherein said polypeptide is capable of dephosphorylating phosphorylated tyrosine residues and derivatives of these PTP polypeptides which substantially retain the ability to dephosphorylate phosphorylated tyrosine residues (column 3, lines 9-21). Covalent derivatives/modifications specifically include fusion proteins comprising native PTPλ sequences and their amino acid sequence variants, such as immunoadhesins (column 6, lines 47-50). The PTPλ-immunoglobulin chimeras can be assembled as multimers. IgM generally exists as a pentamer of basic four units held together by disulfide bonds. IgA globulin may also exist in multimeric form. See column 25, lines 54-64. Ig subtypes like IgA and IgM may give rise to dimeric or pentameric structures, respectively, of the basic Ig homodimer unit. Multimeric immunoadhesins are advantageous in that they can

bind their respective targets with greater avidity than their IgG-based counterparts. See paragraph bridging columns 26-27. Cheng does not teach, in the sense that Cheng does not anticipate, multimeric forms of (PTP)λ generated by using those Fc regions, or portions thereof, of Ig molecules which are usually multivalent, e.g., IgM pentamers and IgA dimers, which comprise a human J chain.

However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to make multimeric forms of LFA-3-Ig fusion proteins generated by using those Fc regions, or portions thereof, of Ig molecules which are usually multivalent, e.g., IgM pentamers and IgA dimers, which comprise a human J chain, as taught by Wallner in view of Chamow and Max, and to modify that teaching by substituting (PTP)λ polypeptides, wherein said polypeptides are capable of dephosphorylating phosphorylated tyrosine residues and derivatives of these PTP polypeptides which substantially retain the ability to dephosphorylate phosphorylated tyrosine residues, as taught by Cheng, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification because multimeric immunoadhesins are advantageous in that they can bind their respective targets with greater avidity than their IgG-based counterparts, and because a J chain polypeptide may be necessary to form and stabilize IgM pentamers and IgA dimers. The invention is prima facie obvious over the prior art.

Claim Rejections - 35 USC § 103

Claims 73, 74, 76, 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Max (AP, cited by Applicants) and Janknecht (Z, Paper No. 24).

Claims 73, 74, 76, 77 are directed to or encompass a targeting molecule that contains (a), forms (b), comprises at least domain 2 of a J chain, and does not contain any of CH1alpha, CH2alpha, CH3alpha, and CL.

Max teaches an isolated nucleic acid molecule encoding a human J chain (page 836, Figure 1) that comprises the amino acid sequence of SEQ ID NOs: 125, 130, 131, 133; 135, and AsnLys. The J chain does not contain any of CH1alpha, CH2alpha, CH3alpha, and CL. Max does not teach a targeting molecule comprising a J chain linked to a biological agent.

Janknecht teaches the production of eukaryotic proteins in a functional state, using eukaryotic expression systems employing vectors designed to express either N- or C- terminally histidine tagged proteins in eukaryotic cells in order to assess their biochemical and functional properties. The histidine tag allows the rapid enrichment of these proteins by metal chelate affinity chromatography in a native and functional state. Furthermore, the small histidine-tag is unlikely to interfere with the natural properties of the synthesized proteins. See Janknecht page 321, Abstract and paragraph bridging columns 1-2. Janknecht teaches vectors that are modified by inserting an oligonucleotide, which encodes a stretch of six His residues (paragraph bridging pages 321-322) and a method of producing the encoded protein (page 322, paragraph bridging columns 1-2). Janknecht does not teach a targeting molecule comprising a J chain linked to a biological agent.

However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to recombinantly express the human J chain nucleic acid molecule, as taught by Max, with a His tag, as taught by Janknecht, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to combine these teachings because the

supply of many eukaryotic proteins which have potential clinical or industrial use is often limited by their low natural availability; gene cloning and expression in can provide a more abundant source of these polypeptides; the advantages of recombinant expression would provide a convenient source of readily purified protein that could be used for structural and/or functional studies; the histidine tag allows the rapid enrichment of these proteins by metal chelate affinity chromatography in a native and functional state. The His tagged J chain could be used in a pharmaceutical composition for the production of antibodies with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make antibodies to the His tagged J chain because the small histidine-tag is unlikely to interfere with the natural properties of the synthesized proteins and because antibodies would allow one of ordinary skill in the art to examine the expression of the J chain protein.

The present specification at page 7 defines a "biological agent" as any molecule that is synthesized by a cell or ex vivo, can be derived from a cell and/or can be demonstrated to modify the properties of a cell. Janknecht teaches that expression of a His tag within a cell. The His tag is clearly "synthesized by a cell." The nature and extent of the derivation in "derived" is unclear. The His tag is "derived from a cell" in the absence of evidence to the contrary. A cell that lacks a His tag has the property of lacking a His tag. The His tag is capable of modifying the properties of a cell insofar as a cell that lacks a His tag has the property of lacking a His tag and a cell that has a His tag has the property of possessing a His tag. A histidine is a portion of a Ig heavy chain.

The invention is prima facie obvious over the prior art.

Claim Rejections - 35 USC § 112

Claim 51 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The nucleotide sequence of SEQ ID NO: 13 and the associated amino acid sequence, differ from the originally filed SEQ ID NO: 13 and associated amino acid sequence. Support for this change cannot be found in the disclosure as originally filed, which raises the issue of new matter.

Claims 64, 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 64, 65 recite the term "intracellular ... enzyme ... secreted from an epithelial barrier" (claim 64). This term is not an art recognized term. Although applicants may act as their own lexicographer to specifically define a term of a claim, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so define that claim term. The term is indefinite because the specification does not clearly define the term. The metes and bounds are not clearly set forth.

Specification

The amendment filed 08/19/2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The nucleotide sequence of SEQ ID NO: 13 and the associated amino acid sequence, which differs from the originally filed SEQ ID NO: 13 and associated amino acid sequence.

Applicant is required to cancel the new matter in the reply to this Office Action.

Conclusion

A J chain encoded by nucleotides 1-213 of SEQ ID NO: 8 is free of the prior art of record.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Martin (V) discloses ICi-2D/IgM, which is an ICAM-1/Ig chimera (Figure 1). the size of the very high molecular weight form is consistent with five dimeric molecules linked by a J chain or six dimeric molecules (page 3563, paragraph bridging left and right columns).

No claims are allowable. Claim 50 is objected to as being dependent upon a rejected base claim.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571) 272-0961.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

David Romeo

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
MARCH 19, 2005

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES	Application No. 09/005,318	Applicant(s) HEIN ET AL.	
	Examiner David S. Romeo	Art Unit 1647	

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒7. Other: Claims 48, 53, 55, 58, 60 recite SEQ ID NOs: 114-140. However, these SEQ ID NOs: are not part of the sequence listing.

Applicant Must Provide:

☒ A substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ A substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

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